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(71) Applicant (for all designated States except US): DI-  
ADENUS, INC. [US/US]: 343 Oyster Point Boulevard,  
South San Francisco, CA 94080 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): MACINA, Roberto,  
A. [AR/US]: 4118 Crescendo Avenue, San Jose, CA 95136  
(US). TURNER, Leah, R. [US/US]: 939 Rosette Court,  
Sunnyvale, CA 94086 (US). SUN, Yongming [CN/US]:  
551 Shoal Circle, Redwood City, CA 94065 (US).

(74) Agents: LICATA, Jane, Massey et al.: Licata & Tyrrel  
P.C., 66 E. Main Street, Marlton, NJ 08053 (US).

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For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.

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(54) Title: COMPOSITIONS, SPLICE VARIANTS AND METHODS RELATING TO BREAST SPECIFIC GENES AND PRO-  
TEINS

(57) Abstract: The present invention relates to newly identified nucleic acid molecules and polypeptides present in normal and neoplastic breast cells, including fragments, variants and derivatives of the nucleic acids and polypeptides. The present invention also relates to antibodies to the polypeptides of the invention, as well as agonists and antagonists of the polypeptides of the invention. The invention also relates to compositions containing the nucleic acid molecules, polypeptides, antibodies, agonists and antagonists of the invention and methods for the use of these compositions. These uses include identifying, diagnosing, monitoring, staging, imaging and treating breast cancer and non-cancerous disease states in breast, identifying breast tissue, monitoring and identifying and/or designing agonists and antagonists of polypeptides of the invention. The uses also include gene therapy, production of transgenic animals and cells, and production of engineered breast tissue for treatment and research.



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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/38739

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12Q 1/68; C12P 21/02; C12N 15/00, 15/12, 15/11; A61K 31/7088, 31/711  
US CL : 536/23.1, 23.5; 435/6, 320.1, 325, 252.3, 69.1; 514/44

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 536/23.1, 23.5; 435/6, 320.1, 325, 252.3, 69.1; 514/44

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Compugen, SEQ ID NO: 73

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GU, J.Z. et al, The human B22 subunit of the NADH-ubiquinone oxidoreductase maps to the region of chromosome 8 involved in branchio-oto-renal syndrome, Genomics, 1996, Vol. 36, No. 1, pages 6-10, see especially page 8, Figure 1.	1-3, 5, 6, 8, and 9
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Y		4 and 10

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

18 August 2004 (18.08.2004)

Date of mailing of the international search report

14 SEP 2004

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Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703)305-3230

Authorized officer

James Martnell

Telephone No. (703) 308-0196

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/38739

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:  
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
  2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
  3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-10 and 15-17.
- Remark on Protest ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

**BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING**

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-10 and 15-17, drawn to nucleic acids, nucleic acid molecular hybridization assays, vectors, host cells; methods for producing polypeptides, kits, vaccines, and methods of treatment using nucleic acids.

Group II, claim(s) 1, 12, and 16-18, drawn to polypeptides, kits, vaccines, and methods of treatment using polypeptides.

Group III, claim(s) 13-15, drawn to antibodies and protein binding assays.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The nucleic acids, vectors, host cells, nucleic acid containing kits, and nucleic acid vaccines of Group I are materially different from the polypeptides, kits containing polypeptide, and polypeptide vaccines of Group II, and the antibodies of Group III. The methods of Group I may be practiced without the products or compositions of Group II or the antibodies of Group III. The methods of Groups I-III may be practiced independently of one another. The polypeptides and vaccines of Group II are materially different from the antibodies of Group III and are not needed to practice the methods of Group III.

Each of the Groups mentions a matter which additional Group for search. Any additional SE of payment of additional search additional Groups to be searched otherwise.

rate and unrelated nucleic acids and/or polypeptides. No need to select for search one SEQ ID NO within the Group(s) requires one additional search fee per SEQ ID NO. In the absence of Group I will be searched. Should applicant pay fee(s) for the selected Group will be searched unless applicant directs

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